

Program Bulletin

93.1

1-08-93

ALFATOXIN SAMPLING AND RECONDITIONING PROCEDURES

I. **PURPOSE** This program bulletin revises aflatoxin sampling procedures and establishes reconditioning procedures for aflatoxin-contaminated corn.

II. **GENERAL INFORMATION** Recently, the grain industry requested the Federal Grain Inspection Service (FGIS) to reconsider its sampling and sample preparation procedures and the Food and Drug Administration (FDA) to reconsider its sampling policy for contaminated lots of corn at export. FDA, FGIS, and the grain industry representatives held several meetings and discussed industry's concerns. From these meetings, FGIS revised its sample preparation procedures, and FDA established a reconditioning and resampling process for aflatoxin-contaminated corn lots at export.

III. **SAFETY** FGIS personnel must abide by all safety and health rules referenced in the Aflatoxin Handbook, Chapter 1, Section 1.3 and Chapter 2, Section 2.4.I.3. FGIS personnel must use protective clothing, gloves, masks, ... etc., when handling a known aflatoxin contaminated lot.

IV. **FGIS SAMPLING PROCEDURES** The revised FGIS sampling procedures for aflatoxin testing service are as follows:

A. Sample Size.

Applicants may request a sample size larger than the minimum sample size indicated in the Aflatoxin Handbook, Chapter 4, Section 4.2. If a larger sample size is requested, obtain the requested quantity.

B. Sample Preparation.

Grind the entire corn sample obtained for aflatoxin testing. Prepare three 500-gram subportions from the ground sample.

Sample Portion

Use

- | | |
|-----------------|---|
| 1. Test Portion | Original Inspection Service |
| 2. File Portion | Review Inspection Service |
| 3. FDA Portion | Retain for FDA analysis if results
Exceed 20 ppb |

When reconditioned lots are resampled in accordance with Section V of this Bulletin, a file portion is not needed. FGIS reinspections/appeals are not permitted for reconditioned lots. If FGIS' original results for a reconditioned lot of corn or screenings exceeds 20 ppb, the FDA sample portion will be used for any subsequent verification of results.

V.
FDA
RECONDITION
GUIDELINE

A. Export Corn Lots.

FDA will permit reconditioning of aflatoxin-contaminated corn lots at export locations by mechanical cleaning under the following conditions:

1. Only one attempt at reconditioning is allowed. The analytical results from the reconditioned lot will be the final determination for disposition of the entire lot.
2. To assure proper reconditioning, the grain company must mechanically clean the lot at a cleaning rate not to exceed 50 percent of the rated cleaner capacity.
3. FGIS must oversee the cleaning process, sample the reconditioned lot (cleaned corn) using a diverter type mechanical sampler, and analyze the samples for aflatoxin.
4. FGIS must sample the cleanings/screenings using the most practical procedures available and test the cleanings and/or screenings for aflatoxin contamination.

B. Domestic Corn Lots.

At interior locations, the local FDA office may modify the above reconditioning procedures to provide for a cost effective process.

VI.
DISPOSITION
POLICY

The grain industry must comply with FDA policy regarding the disposition of corn and screenings resulting from the reconditioning process. In general, disposition will occur as follows:

1. Cleanings/screenings may be used for animal feed if the aflatoxin content meets FDA feed guidelines. The screenings may not re-enter food channels in any fashion.

2. Reconditioned (cleaned) corn with less than 20 ppb aflatoxin may be handled without restrictions. When the reconditioning process fails and the corn continues to exceed the 20 ppb level, disposition is based on current FDA policy.

Contact the local FDA office regarding other questions concerning specific disposition action.

VII.
FGIS
RESPONSI-
BILITIES

A. General Responsibilities at Export Locations.

FGIS plays an important role in assisting FDA in the reconditioning process at export port locations. When positive lots are identified, FGIS' responsibilities include the following:

1. Report actionable lots to the local FDA field office in accordance with the Aflatoxin Testing Handbook.
2. Identity preserved actionable lots may be held in railcars or barges if elevator so wishes, prior to reconditioning.
3. Monitor the reconditioning process at the grain facility.
4. Sample and test reconditioned lots (cleaned corn and screenings) for aflatoxin. When sampling screenings, use the most practical method available to obtain a representative sample.
5. Identity preserve reconditioned lots and screenings. The screenings are not considered a reconditioned lot.
6. Report aflatoxin results of reconditioned lots and screenings to FDA.
7. Send reconditioning information to the area program chief's office.

To facilitate the reconditioning process, field office managers (FOM) shall work with the grain facility representatives and develop a standard operating procedure (SOP) for reconditioning aflatoxin-contaminated corn.

FOM's should review the SOP with local FDA officials before implementing the reconditioning process, unless instructed otherwise by FDA.

B. General Responsibilities at Domestic Locations.

FOM's servicing interior locations should contact their local FDA office to discuss and determine responsibilities for managing the reconditioning process. Agencies and affected grain companies are encouraged to participate in these discussions to facilitate the development of an SOP.

C. Data Collection.

When a contaminated corn lot is reconditioned according to the FDA guidelines, report the following information to the appropriate FGIS area program chief using Form FGIS-992:

1. Date reconditioned.
2. Grain Elevator/Location.
3. Type of Sample/Carrier.
4. Original Results.
5. Reconditioned Whole Grain Results.
6. Cleanings/Screenings Results.
7. Size of Cleaner Screens used to Recondition the Lot.
8. Elevator Set-up Information.

Please direct any questions regarding reconditioning aflatoxin contaminated corn to the Standards and Procedures Branch.

David R. Shipman
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